REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-3, 5, 8, 9, and 28-36 are currently under consideration. Claims 1, 3, 28-33, 35, and 36 are amended and claim 2 is cancelled without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

Support for the amendment to claim 1 can be found in cancelled claim 2. The amendments to claims 28-33, 35, and 36 remove their dependency on withdrawn claims. No new matter is added.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to clarify the scope of protection to which Applicants are entitled.

II. THE REJECTION UNDER 35 U.S.C. § 103(a) IS OVERCOME

Claims 1-3, 5, 8, 9, 28-33, 35, and 36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Shibata *et al.* (J Immunol 164: 1314-21, 2000; hereinafter "Shibata") in view of Clinical Report (Pediatrics 100: 143-152, 1997) as evidenced by the specification of the present application, the Sigma Chitin powder product sheet, WO 97/20576, Kim *et al.* (J Dent Child 71: 126-130, 2004), and U.S. Patent No. 6,080,762. The rejection is respectfully traversed.

The Office Action contends that the previous arguments submitted by Applicants were not found to be persuasive, as nasal/intranasal administration is being increasingly recognized as routes for delivering drugs in allergy treatment since this route provides rapid and relatively painless drug absorption resulting in rapid central nervous system effect. According to the Office Action, surfactants and excipients are well know in the art for nasal administration, and the active dosage of chitin microparticles of 5mg/20g in the previous invention is equivalent to 0.1mg/kg taught in Shibata.

In response, Applicants initially draw attention to amended claim 1, which recites a method of treating an allergy comprising administering intranasally or by inhalation a therapeutically effective amount of a chitin microparticle (CMP) preparation, wherein the allergy is selected from the group consisting of seasonal respiratory allergies, allergy to aeroallergens, and asthma. With this in mind, Applicants assert that one skilled in the art would not recognize that Shibata teaches a method of treating an allergy as recited in the instant claims. In support of this argument, Applicants enclose a Declaration under 37 C.F.R. § 1.132 by Dr. Peter Strong.

Dr. Strong argues that Shibata induces ragweed allergy challenge by intratracheal introduction of the ragweed allergen, which bypasses the upper respiratory system. As a result, Shibata does not demonstrate a method of treating seasonal respiratory allergies or allergies to aeroallergens because these allergies involve inhalation of pollens, spores, animal dander, etc. Further, Shibata only shows how its method can affect serum IgE levels and lung eosinophilia, but does not discuss how the method can alter respiratory function. Clinical Reports notably does not remedy these deficiencies. Thus, the skilled artisan would not consider that Shibata and Clinical Reports teaches or suggests a method of treating allergies as instantly claimed.

In contrast, the studies of the present invention involve challenging the subjects with intranasal introduction of allergens, which thereby mimics inhalation of the allergens and properly involves the upper respiratory system (see Example). The Declaration provides additional data that shows the efficacy of the methods of the invention against allergies induced by grass, tree, and ragweed pollens, and animal dander, and against asthma. Moreover, the Declaration provides results from whole body plethysmography which indicates respiratory function. Hence, unlike Shibata and Clinical Reports, the present invention indeed demonstrates a method of treating seasonal allergies, allergies to aeroallergens, and asthma as recited in the instant claims.

In addition, Applicants assert that one skilled in the art would not combine the secondary references with Shibata and Clinical Reports. As discussed in the Declaration, the secondary references relate to soluble drugs rather than insoluble drugs. For instance, Kim relates to how intranasal delivery of midazolam, a water-soluble drug, can potentially result in rapid absorption, while the '762 patent relates to Raloxifene, which is also a soluble drug. One skilled in the art would therefore not apply the teachings of Kim and the '762 patent as support or motivation for administering insoluble CMP intranasally or by inhalation.

Finally, Applicants assert that the methods of the present invention exhibit additional advantages that were not considered in the cited references. As discussed in the Declaration, the present invention administers the CMP composition intranasally in order to deliver its immune modulating properties specifically to the site of allergic inflammation. Further, if the CMP composition produces an adverse reaction, removal of the composition can be more easily achieved if it was delivered by nasal application, *i.e.*, by irrigation or sneezing, then if it was delivered by other routes, *e.g.*, orally. Neither Shibata nor Clinical Reports teaches or suggests that intranasal administration will advantageously direct the immune effects to inflamed sites.

Thus, the skilled artist would not recognize that the combination of Shibata and Clinical Reports renders the instant invention unpatentable. Accordingly, reconsideration and withdrawal of the Section 103 rejection are respectfully requested.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview with the Examiner and SPE are respectfully requested and the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks and amendments herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,
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